

taken into the human body or animal body shall, in addition to the requirements of paragraph (a) of this section submit the following data, where reasonably available:

(i) Summary laboratory reports of data obtained in subacute and chronic animal studies where the data pertain to the absorption, distribution, metabolism and excretion of substances in question;

(ii) A median lethal dosage (LD50) determination conducted in one additional species. Of the two LD50 determinations required for persons submitting exemption requests under this part, one should be conducted in a non-rodent species;

(iii) Summary reports of data obtained in human studies designed to measure the absorption, distribution, metabolism, and excretion of substances in question; and

(iv) Data indicating, insofar as is known, the mechanism of action of the substance in question and the mechanism by which expected toxicological effects occur. If these mechanisms are unknown, the petition should state this.

(2) Petitioners submitting exemption requests for substances normally used on or taken into the human or animal body shall, in addition to the requirements of paragraphs (a) and (b)(1) of this section, submit an evaluation of the pharmacology and toxicology of the substance in question based on reasonably available medical and scientific literature. The evaluation should be a comprehensive one, and should include proper literature citations. To the extent possible, information submitted by the petitioner justifying an exemption based on the medical and scientific literature will be evaluated under the criteria specified in §1702.9(a) for evaluating experimental data. In certain cases where the experimental data specified by §1702.9 (a) and (b) are unavailable, the medical and scientific literature may justify granting an exemption, particularly where the pharmacology and toxicology of the substance is well documented in the literature.

(c) *Optional data criteria for petitions involving substances not used in or on the human or animal body.* The following

types of data, although often not generated for household substances not normally used in or on the human or animal body, may be available to a petitioner and should, where reasonably available, be submitted.

(1) Summary laboratory reports of data obtained in subacute and chronic animal studies where such data pertain to the absorption, distribution, metabolism, and excretion of the substance in question;

(2) Results of median lethal dosage (LD50) studies conducted in additional species of animals; and

(3) Any additional experimental studies relevant to the exemption request which would provide the Commission with additional means of assessing the hazards to children of the product for which exemption is sought.

§ 1702.10 Human experimental data involving the testing of human subjects.

Any human experimental data submitted with a petition requesting an exemption under this part shall include a statement establishing that adequate measures have been taken to ensure against psychological or physical injury to the subject of the human studies. The Commission considers its regulations concerning the protection of human subjects (16 CFR part 1028) to be an example of measures that are adequate to ensure against psychological or physical injury to human subjects.

§ 1702.11 Product specifications.

Each petition for an exemption shall include:

(a) A complete quantitative formula for the product, including inert ingredients, diluents, and solvents. (Petitioners should refer to §1702.6 for information regarding trade secrets.)

(b) A listing of all physical forms or dosage forms (whichever is appropriate) in which the product is available.

§ 1702.12 Packaging specifications.

Each petition for an exemption shall include the following information for each form of the product for which an exemption is sought:

(a) A description of the packaging currently in use including the name of

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the manufacturer of the package and all specifications for the package.

(b) A complete packaging description including any carton or wrapping in which the product is offered to the consumer,

(c) A description of each size in which the product is offered, including physical form, color and flavoring, and

(d) An empty sample of each type and size of package petitioned for exemption and, in the case of drugs, a designation of those packages intended to be used in dispensing the product to the consumer for household use.

§ 1702.13 Labeling and packaging samples.

Each petition for an exemption under this part shall include a sample of the label and complete packaging for each size in which each form of the product for which an exemption is sought is packaged. This shall include the immediate container labeling, any package inserts, and other carton or wrapping labeling in which the product is offered to the consumer. In the case of drugs, each petition shall be accompanied by labeling on the outer carton or wrapping in which the product is offered to the retailer, as well as samples of the promotional and advertising information for the product.

§ 1702.14 Marketing history.

Each petition for an exemption under this part shall include a statement of the marketing history of the substance for which an exemption is requested. The marketing history dates from the year in which each form of the product was introduced onto the market. The marketing history shall include the total number of units of each form or strength and package size of the product distributed since the product was introduced onto the market. In the case of prescription drugs, the average prescription size for the product should also be indicated, if known.

§ 1702.15 Petitions alleging the incompatibility of child resistant packaging with the particular substance petitioned for exemption.

(a) Where the petition for an exemption is based upon an allegation that the applicable special packaging stand-

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ard is incompatible with the particular substance or would seriously and adversely compromise the utility or stability of a substance, the petitioner shall submit adequate evidence to support the allegation.

(b) If the allegation of incompatibility is based upon the fact that package choice is limited by a new drug application filed with the FDA, the petition shall state the limitation of package choice and a description of a time schedule to revise the NDA in order to allow additional package choice.

(c) If the allegation of incompatibility is based upon the fact that the shelf life of the product limits package choice, the petition shall outline the particular limitation and shall include a description of a time schedule to re-establish shelf-life data.

§ 1702.16 Petitions requesting an exemption for a drug or a new drug.

(a) Where the petition requests an exemption for a drug, as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), the petitioner shall include those reports required to be filed under the Food and Drug Administration's Adverse Reaction Reporting Program.

(b) [Reserved]

[45 FR 13064, Feb. 28, 1980, as amended at 66 FR 40115, Aug. 2, 2001]

§ 1702.17 Granting petitions.

Where the Commission determines that reasonable grounds for an exemption are presented by the petition, the Commission shall publish, in the FEDERAL REGISTER, a proposed amendment to the listing of substances requiring special packaging under § 1700.14(a). "Reasonable grounds" for publishing a proposed exemption are information and data sufficient to support the conclusion that:

(a) The degree or nature of the hazard to children in the availability of the substance, by reason of its packaging, is such that special packaging is not required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance, or

(b) Special packaging is not technically feasible, practicable, or appropriate for the subject substance, or